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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,400

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Jouko Savolainen

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EXAMINER

TSAY, MARSHA M

ART UNIT

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1656

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,400	Applicant(s) SAVOLAINEN ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,11-22,25-27 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) 6-8,17 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,11-16,18-22,25,26 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This Office action is in response to Applicants' remarks received November 30, 2007. Claims 3, 9-10, 23-24, 28-29 are canceled. Claims 6-8, 17, 27 are withdrawn. Claims 1-2, 4-5, 11-16, 18-22, 25-26, 30-34 are currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Priority: The priority date is October 15, 2003.

Objections and Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-5, 11-16, 18-22, 25-26, 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependent claims recite a protein network formed by disulfide bonds between modified proteins and unmodified proteins. It is unclear what is meant by a "modified" protein; the exact nature of the modification should be recited.

Claims 4, 26 recite said modified protein comprises whey protein and fractions of modified whey protein. It is unclear how both "whey protein" and fractions of "modified whey protein" can be modified. It is generally known that "whey protein" is an unmodified protein. Further clarification is requested.

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Claim 5 recites said modified protein has been sulfonated by contacting it with a sulfite ion forming agent. As currently written, it is unclear if the modified protein is treated with a sulfite ion forming agent or if claim 5 is reciting a procedure for preparing a modified protein. Further clarification is requested.

Claims 11 and 30 recite said film has been formed on a substance. The claims are redundant because it is generally accepted that film (by inherency) is formed on some kind of surface or substance.

Claim 20 recites modifying the unmodified protein by contact with a sulfite ion forming agent to obtain free sulfhydryl groups. It is unclear if the free sulfhydryl groups should be obtained for both "modified proteins" and "unmodified proteins." Since the method appears to be directed to forming S-S bonds, then both modified and unmodified proteins must have free -SH groups. Further clarification is requested. Further, in claim 20 line 5, it is unclear if "the protein" refers to "modified protein" or some other protein. Also, line 9 recites forming disulfide bonds between proteins, it is unclear which proteins are being referred to.

Claims 21-22, 25-26, 30-34 are included in this rejection because they are dependent on claim 20 and fail to cure the defect.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-2, 4-5, 11-16, 18-22, 25-26, 30-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Krochta et al. (US 5543164) in view of Krochta et al. (US 6869628).

Krochta et al. ('164) disclose water-insoluble protein-based coatings and films and methods for their preparation (col. 4 lines 33-35). Krochta et al. ('164) disclose the first step is the formation of an aqueous denatured protein solution (col. 5 lines 12-13). Preferred proteins include whey protein (col. 5 lines 22-23). The thiol-disulfide exchange can be effected by a chemical treatment or an enzymatic treatment (col. 5 lines 25-26). When a chemical treatment is used, the protein is brought into contact with a chemical agent for a period of time sufficient to initiate disulfide arrangements, wherein the chemical agents include sulfites (col. 5 lines 37-43). Further, thiol-disulfide exchange in a protein can also be performed enzymatically (col. 5 lines 47-48). The result of these reactions is a solution of a denatured protein having a mixture of intermolecular and intramolecular disulfide crosslinks (col. 5 lines 51-53). Krochta et al. ('164) do not teach a mixture of denatured and non-denatured proteins to form a protein-based film.

Krochta et al. ('628) disclose methods of making water-insoluble films and coatings from water based WPI (whey protein isolate) solutions (col. 5 lines 3-5). Krochta et al. further disclose that mixtures of various proportions of denatured and non-denatured proteins can be used to impart any desired level of protection from moisture (col. 5 lines 11-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a whey protein-based film by chemical and/or enzymatic treatment according to the teachings of Krochta et al. ('164) and mixing in various proportions of denatured and non-denatured whey protein as suggested by Krochta et al. ('628) in order to create a protein-based film and/or coating with the desired level of protection (claims 1-2, 4-5,

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20-22, 25-26). The motivation to do so is given by Krochta et al. ('628) which teach that mixtures of various proportions of denatured and non-denatured proteins can be used to make protein-based films and/or coatings with levels of protection, i.e. moisture.

While Krochta et al. ('164) do not teach a pH of 7, Krochta et al. ('164) disclose that the enzymatic treatment can be carried out with enzymes including sulfhydryl oxidase, peroxidase, which function optimally at a pH of 7 (claims 1, 20).

Krochta et al. ('628) also disclose a method of providing an edible coating to a food comprising coating said food with a protein-based film (col. 23 lines 50-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the protein-based film of Krochta et al. ('164) in view of Krochta et al. ('628) on a food product because Krochta et al. ('628) suggest that an edible protein-based coating can be used to coat food to make it more appealing or to protect it from moisture (claims 11-16, 18-19, 30-34).

In their remarks, Applicants assert that the combination of references does not disclose all claim elements of amended claim 1. In particular, claim 1 now recites that the network contains from about 2 to about 4 free sulfhydryl groups per protein. Support for this amendment is found in the specification on page 13, lines 14-20. Applicants further assert that Krochta '164 also appears to teach that any remaining free thiol groups should be oxidized, col. 5, lines 44-48. Applicants submit that this teaches away from amended claim 1. Applicants' arguments have been fully considered but they are not persuasive.

In col. 5, lines 44-48, Krochta '164 discloses that the remaining free thiol groups can be oxidized by exposure to atmospheric oxygen or by reaction with oxidizing agents. It should be

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noted that Krochta '164 does not disclose that said remaining free thiol groups should be oxidized. It would be reasonable for one of ordinary skill to recognize that while Krochta '164 suggests that the remaining free thiol groups can be oxidized, Krochta '164 does not necessarily teach that they have to be oxidized. It is known in the art that the texture of WPI (whey protein isolate) gels and SH/S-S interchange reactions are correlated (p. 161, Shimada et al. 1989 J Agric Food Chem 37: 161-168). Shimada et al. further disclose that the low elasticity of a whey protein gel may reflect a small number of intermolecular S-S bonds in the gel network (p. 167) and confirm that intermolecular S-S bonds due to SH/S-S interchange reactions are responsible for gel network formation and for high gel elasticity (p. 168). Therefore, it would be reasonable for one of ordinary skill to recognize that not all the remaining free thiol groups of the whey protein-based film of Krochta '164 in view of Krochta '628 needs to be oxidized, as evidenced by Shimada et al. Depending on the desired degree of elasticity, one of ordinary skill would recognize that the number of free sulfhydryl groups can be adjusted accordingly in the protein network of the whey protein-based film of Krochta '164 in view of Krochta '628. Therefore, the instant claims remain rejected under 35 U.S.C. 103(a) as unpatentable over Krochta '164 in view of Krochta '628, as evidenced by Shimada et al.

Applicants further assert that there is no motivation to combine the references to arrive at claim 20. Claim 20 has been amended to require the use of sulfite ion forming agent at a pH of 7 or below. Applicants assert that page 9 of the previous Office action states that enzymatic treatment can be carried out with enzymes that function optimally at a pH of 7. Applicants submit that while this disclosure may provide motivation to use a pH of 7 when enzymes are

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used to form the disulfide bonds, it does not provide motivation to use a pH of 7 if enzymes are not used. Applicants' arguments have been fully considered but they are not persuasive.

As noted above, Krochta '164 discloses that the thiol-disulfide exchange can be effected by a chemical treatment or an enzymatic treatment (col. 5 lines 25-26). Krochta '164 further disclose that the enzymatic treatment can be carried out with enzymes including sulfhydryl oxidase, peroxidase, which one of ordinary skill would recognize function optimally at a pH of 7. Since Krochta '164 also disclose that the thiol-disulfide exchange can also be effected by chemical treatment, it would be reasonable for one of ordinary skill to correlate the chemical treatment conditions with the enzymatic treatment conditions since both sets of conditions are performed for the same intended purpose, i.e. thiol-disulfide exchange. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). “The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”; In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). In this instance, it would be reasonable for one of ordinary skill to use a pH of 7.0 under chemical treatment conditions since Krochta '164 suggests that said pH can be used under enzymatic treatment conditions for the same intended purpose.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

March 11, 2008